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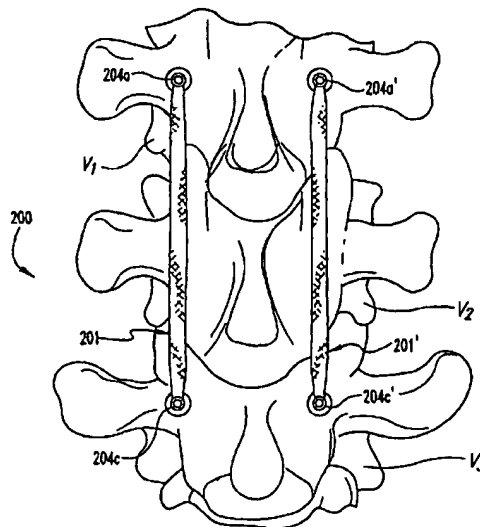
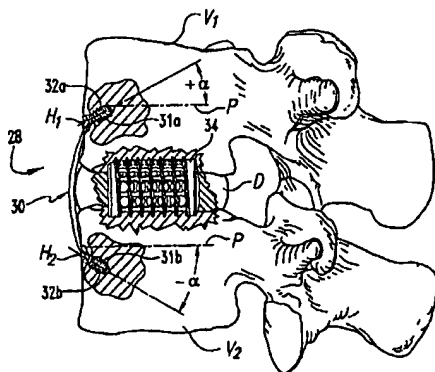
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(54) Title: FLEXIBLE SYSTEMS FOR SPINAL STABILIZATION AND FIXATION



(57) Abstract: Systems for spinal stabilization and fixation replace, reconstruct or augment the spinal ligamentous and/or bony tissues resected during surgical procedures. The spinal stabilization system includes at least an implant configured to span the intervertebral disc space with at least one of its ends attached to a respective vertebral body by at least one anchor. The system has a low profile conformable to the spinal anatomy.

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FLEXIBLE SYSTEMS FOR SPINAL STABILIZATION AND FIXATION

BACKGROUND

5 The present invention is directed devices and methods for use in spinal surgery, and more particularly to devices and methods for stabilizing the spine. Various spinal surgical procedures require access of a subject disc space or vertebral body, such as for the repair of a herniated disc or vertebral body, the insertion of one or more interbody fusion devices, interbody spacers, or artificial discs. In order to access a spinal
10 column, one or more spinal ligaments and bony tissue may have to be severed or at least partially resected to allow insertion of devices and/or surgical instruments into or to the disc space or vertebral body. It also may be desirable to augment or replace existing spinal ligaments and bony tissue. Posterior or anterior rigid metal constructs can also be used to stabilize the spinal column after these techniques are completed.

15 Rigid metal plates or rods on the anterior, antero-lateral, lateral or posterior portions of the spinal column segment are in close contact with and exposed to the adjacent vasculature and tissue. It is desirable that the potential for screw back out, loosening, bending of the construct, and stress shielding be reduced or eliminated in view of this close contact with the vasculature and the surrounding tissue.

SUMMARY OF THE INVENTION

20 The present invention is directed systems and methods for spinal stabilization and fixation. The systems are useful in the replacement, reconstruction or augmentation of spinal ligamentous or bony tissues, and also in resisting the tensile and rotational loading applied thereto by spinal motion.

25 In one form, the spinal stabilization systems include at least an elongated implant configured to span the intervertebral disc space with its ends attached to a respective vertebral body. The ends of the implant can be placed in tunnels formed in the adjacent vertebrae. The implant can have a substantially flexible yet substantially inelastic body with a low profile capable of conforming to the spinal anatomy. The anchors used to
30 attach the ends of the implant to the vertebrae can be at least partially concealed in the vertebral body to which it is engaged, further reducing the profile of the device. Examples

of suitable anchors include interference screws, suture anchors, bone screws, buttons, pin fasteners, and staples. It is further contemplated that the implant and anchors can be made from nonresorbable or resorbable material.

In one technique, the stabilization system can be attached to and stabilize the anterior portion of the spinal column. The stabilization system can also be attached to and stabilize the lateral or antero-lateral portion of the spinal column. In another technique, the stabilization system is attached to a posterior portion of the spinal column via anchors engaged to the vertebrae at any one of a number of locations, including but not limited to the facets, pedicles, pars, transverse processes, or spinous processes.

There are also various methods for securing a flexible implant to adjacent vertebral bodies in which the anchor and at least a portion of the implant is placed in a tunnel formed in the vertebral body. The attachment techniques provide a low profile system that reduces exposure and contact with the adjacent anatomic structures.

These and other forms, aspects, embodiments, features and advantages of the present invention will be apparent from the following description of the illustrated embodiments.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1 is a side elevational view in partial section of a spinal column segment having an interbody fusion device inserted into the disc space and one embodiment spine stabilization system attached to the vertebral bodies.

Fig. 2 is a side elevational view in partial section of a spinal column segment having an artificial disc inserted into the disc space and another embodiment spine stabilization system attached to the vertebral bodies.

Fig. 3 is an anterior elevational view of a spinal column segment having another embodiment spine stabilization system attached thereto.

Fig. 4 is an anterior view of a spinal column segment having a further embodiment spine stabilization system attached thereto.

Fig. 5 is a side elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

Fig. 6 is a side elevational view in partial section of a spinal column segment having a further embodiment spine stabilization system attached thereto.

Fig. 7 is a perspective view of one embodiment of an anchor for attaching spine stabilization systems to vertebral bodies.

5 Fig. 8 is a side elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

Fig. 9 is a side elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

10 Fig. 10 is a side elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

Fig. 11 is a side elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

Fig. 12 is an anterior elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

15 Fig. 13 is an anterior elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

Fig. 14 is a side elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

20 Fig. 15 is a side elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

Fig. 16 is an anterior elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

Fig. 17 is an anterior elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

25 Fig. 18 is an anterior elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

Fig. 19 is an anterior elevational view in partial section of a spinal column segment having another embodiment spine stabilization system attached thereto.

30 Fig. 20 is a side elevational view of a spinal column segment having a posterior spine stabilization system attached thereto.

Fig. 21 is a side elevational view of a spinal column segment having another embodiment posterior spine stabilization system attached thereto.

Fig. 22 is a posterior elevational view of a spinal column segment having another embodiment posterior spine stabilization device attached thereto.

DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the illustrated embodiments and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any such alterations and further modifications of the invention, and any such further applications of the principles of the invention as illustrated herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention includes spine stabilization systems in which flexible implants are anchored to the adjacent vertebrae. The stabilization systems have application in stabilizing the anterior, antero-lateral, lateral and/or posterior portions of a spinal column segment including one or more vertebral levels. The implants have a low profile and are conformable to the spinal anatomy to minimize intrusion into the surrounding tissue and vasculature. The implants attach to vertebrae and prevent separation of the vertebrae while allowing normal extension and articulation of the spinal column segment. Portions of the implants and the anchors attaching the implant to vertebrae can be at least partially or fully embedded within the vertebrae to minimize intrusion into the surrounding tissue and vasculature.

It is contemplated that the implants of the spine stabilization systems described herein can be made from resorbable material, nonresorbable material and combinations thereof. In one example, resorbable implants can be used with interbody fusion devices since a permanent exterior stabilization may not be desired after fusion of the vertebrae. It is also contemplated that the anchors used to attach the implants to the vertebrae can be made from resorbable material, nonresorbable material, and combinations thereof. The implants can be flexible, tear resistant, and/or suturable. The implant can be fabricated from synthetic flexible materials in the form of fabrics, non-woven structures, two or three dimensional woven structures, braided structures, and chained structures. The

implants can also be fabricated from natural/biological materials, such as autograft or allograft, taken from patellar bone-tendon-bone, hamstring tendons, quadriceps tendons, or Achilles tendons, for example. Growth factors or cells can be incorporated into the implant for bone ingrowth and bony attachment or for soft tissue ingrowth. Possible growth factors that can be incorporated include transforming growth factor 1, insulin-like growth factor 1, platelet-derived growth factor, fibroblast growth factor, bone morphogenetic protein, LIM mineralization protein (LMP), and combinations thereof. Possible implant materials include synthetic resorbable materials such as polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass and combinations thereof. Possible implant materials also include natural resorbable materials such as autograft, allograft, xenograft, soft tissues, connective tissues, demineralized bone matrix, and combinations thereof. Possible implant material further include nonresorbable materials such as polyethylene, polyester, polyvinyl alcohol, polyacrylonitrile, polyamide, polytetrafluorethylene, poly-paraphenylene terephthalamide, cellulose, shape-memory alloys, titanium, titanium alloys, stainless steel, and combinations thereof.

The spine stabilization systems described herein include anchors to attach the implant to the vertebrae. It is contemplated the anchors can be, for example, interference screws or anchors, gull anchors, suture anchors, pin fasteners, bone screws with spiked washers, staples, and buttons. It is contemplated that the anchors can be made from resorbable materials, nonresorbable materials, and combinations thereof. Possible synthetic resorbable materials include polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass, and combinations thereof. Possible natural resorbable materials include cortical bone, autograft, allograft, and xenograft. Possible nonresorbable materials include carbon-reinforced polymer composites, shape-memory alloys, titanium, titanium alloys, cobalt chrome alloys, stainless steel, and combinations thereof.

Referring now to Fig. 1, there is shown a spine stabilization system attached to vertebrae V1 and V2. Stabilization system 28 includes a flexible implant 30 that extends along the anterior faces of vertebrae V1 and V2, and is attached to first vertebra V1 and the second vertebra V2. A fusion device 34 has been inserted into disc space D for fusion of vertebra

V1 and vertebra V2. Implant 30 can resist extension, flexion, and/or lateral bending loads created by motion of the spinal column depending on the location or locations of the spinal column segment on which the implant is positioned.

Flexible implant 30 has a first end 31a and an opposite second end 31b. Vertebra V1 includes a first opening H1 in its anterior face and a first tunnel extending therefrom. Vertebra V2 has a second opening H2 in its anterior face and a second tunnel extending therefrom. The ends 31a and 31b are inserted into respective ones of the first and second tunnels through openings H1 and H2. An anchor 32a is inserted through opening H1 and into the tunnel of vertebra V1 to secure end 31a to vertebrae V1. Similarly, an anchor 32b is inserted through opening H2 and into the tunnel of vertebra V2 to secure end 31b to vertebrae V2. Anchors 32a, 32b are illustrated as threaded interference screws that are embedded into vertebral bodies V1 and V2 so that they do not protrude from the anterior faces of vertebrae V1 and V2. However, as with the other implants discussed herein, other anchors and anchoring techniques described herein could also be employed with implant 30.

Interference anchors 32a, 32b can be oriented at an angle \pm @ with respect to the axial plane P of spinal column that provides a smooth transition for implant 30 as it enters openings H1 and H2 of vertebrae V1 and V2. This reduces stress concentrations at the junction between the implant and the vertebrae. In one embodiment, angle @ is about 45 degrees. Other embodiments contemplate angular orientations that range from 0 degrees to about 80 degrees and from about 25 degrees to 65 degrees. As shown in Fig. 3, implant 30 has a reduced lateral width W1 that minimizes the lateral intrusion of implant 30 into the surrounding tissue.

The ends of implant 30 and the other implants described herein can be provided with pigtailed or other extensions of reduced size for insertion through the openings and tunnels formed in the vertebrae. It is also contemplated that the ends of the implant can include eyelets, holes, loops or other configuration suitable for engagement with an anchor.

Referring now to Fig. 2, a spine stabilization system 28' similar to system 28 includes an implant 30 with opposite ends 31a and 31b attached to vertebra V1 and V2, respectively. An artificial disc 38 is placed in disc space D. Implant ends 31a and 31b are

attached to gull anchors 36a and 36b, respectively. Gull anchors 36a, 36b are placed through respective ones of openings H1 and H2 and embedded in tunnels formed in vertebrae V1 and V2, respectively, along with the corresponding ends 31a, 31b of implant 30. Gull anchors 36a, 36b have wings that are pivotable toward their shaft of the anchor during insertion and are pivotable laterally away from the anchor shaft to resist pullout of the anchor from vertebra after insertion therein.

Referring now to Fig. 4, another embodiment spine stabilization system 40 is illustrated attached to vertebrae V1 and V2. System 40 includes an implant 41 attached along the anterior faces of vertebrae V1 and V2. Implant 41 has a width W2 for attachment of two anchors to each end of implant 41. The width W2 also provides greater coverage of the annulus tissue surrounding disc space D. Anchors 44a and 44b are attached to corners 42a and 42b, respectively, of implant 41 to secure it to vertebra V1. Anchors 44c and 44d are attached to corners 42c and 42d, respectively, of implant 41 to secure it to vertebra V2.

Referring now to Figs. 5-7 there are shown two additional embodiments of a spinal stabilization system attached to vertebrae V1 and V2. In Fig. 5 stabilization system 50 includes an implant 51 extending along the anterior faces of vertebrae V1 and V2. Implant 51 has a first end 52a attached to vertebra V1 and an opposite second 52b attached to vertebra V2. Opening H1 opens adjacent to or through the vertebral endplate of vertebra V1, and a first tunnel extends therefrom in vertebra V1 to opening H2 at its anterior face. First end 52a of implant 51 is placed into opening H1 and through the tunnel and attached to vertebra V1 with anchor 54a at opening H2. A second tunnel is formed in vertebra V2 between opening H3 adjacent to or through the vertebral endplate of vertebra V2 and opening H4 at its anterior face. Second end 52b of implant 51 is placed into opening H3 and through the second tunnel and attached to vertebra V2 with anchor 54b at opening H4.

In one embodiment, anchor 54 is a button or flange member that is secured to the ends of implant 51 and abuts against the anterior face of the respective vertebra. As shown in Fig. 7, anchor 54 has a bearing member 56 with a first flange 57 and an opposite second flange 58. Flanges 57, 58 are sized larger than openings H2, H4 and abut against

the face of the vertebra around the respective opening in order to secure implant 51 to the vertebra.

In one embodiment, attachment loop 59 is attached to bearing member 56 to secure implant 51 thereto. Attachment loop 59 can extend into the tunnel adjacent the respective opening H2, H4. Implant 51 can be looped around attachment loop 59 as shown in Fig. 7, or attachment loop 59 can extend through the body of implant 51 like a suture. It is contemplated that attachment loop 59 can be, for example, a tether, cable, or wire. In another embodiment, not attachment loop is provided, but rather the ends of implant 51 extend through openings or slots provided in respective ones of the anchors 54a, 54b and are secured thereto by tying, knotting, looping or otherwise fixing the ends of implant 51 to the adjacent anchor 54a, 54b.

In Fig. 6 stabilization system 60 includes an implant 61 having a first end 62a attached to vertebra V1 and an opposite second 62b attached to vertebra V2. A first tunnel is formed in vertebra V1 between opening H1 at the lower portion of the anterior face of vertebra V1 and opening H2 at the upper portion of the anterior face of vertebra V1. First end 62a of implant 61 is placed into opening H1 and through the tunnel for attachment to vertebra V1 with anchor 54a at opening H2. A second tunnel is formed in vertebra V2 between opening H3 at the upper portion of the anterior face of vertebra V2 and opening H4 at the lower portion of the anterior face of vertebra V2. Second end 62b of implant 61 is placed into opening H3 and through the second tunnel for attachment to vertebra V2 with anchor 54b at opening H4.

It is contemplated that implants 51, 61 or other implants described herein can be provided in multiple segments, of which each segment is attached to a respective one of the vertebrae V1 and V2. The multiple implant segments can be attached to one another adjacent disc space D by suturing, stapling, fusing or otherwise securing the ends of the implant segments together to form a single implant 51, 61. For example, implant 51 includes an upper segment 51a attachable to vertebra V1 and a lower segment 51b attachable to vertebra V2. Upper segment 51a is attached to lower segment 51b at overlap region 51c.

Referring now to Fig. 8 another embodiment spine stabilization system 70 is attached to vertebrae V1 and V2. System 70 has an implant 71 that extends between

vertebrae V1 and V2. Implant 71 has opposite ends 72a and 72b that are positioned in notches N1 and N2 formed in the anterior faces of vertebrae V1 and V2, respectively. Implant 71 has first end 72a attached to vertebra V1 via first anchor 74a in notch N1. Notch N1 is formed in vertebra V1 to recess the head of anchor 74a below the anterior face of vertebra V1, minimize or eliminating its protrusion into the adjacent tissue. Anchor 74a is illustrated in the form of a threaded screw that extends through a spiked washer 76a. The screw and spikes of washer 76a extend through end 72a of implant 71 and into vertebra V1.

Implant 71 has opposite second end 72b attached to vertebra V2 via second anchor 74b in notch N2. Notch N2 is formed in vertebra V2 to recess the head of anchor 74b below the anterior face of vertebra V2, minimizing or eliminating its protrusion into the adjacent tissue. Anchor 74b is illustrated in the form of a threaded screw that extends through a spiked washer 76b. The screw and spikes of washer 76b extend through end 72b and into vertebra V2.

Referring now to Fig. 9 another embodiment spine stabilization system 80 is attached to vertebrae V1 and V2 with anchors 74a, 74b. Anchors 74a, 74b include spiked washers 76a, 76b and a bone screw extending therethrough such as discussed above. System 80 has an implant 81 that extends along and is conformable to the anterior faces of vertebrae V1 and V2. Implant 81 has a first end 82a attached to vertebra V1 via first anchor 74a. The screw and spikes of washer 76a extend through end 82a and into vertebra V1 with the head of anchor 74a abutting against the anterior face of vertebra V1. Implant 81 has an opposite second end 82b attached to vertebra V2 via second anchor 74b. The screw and spikes of washer 76b extend through end 82b and into vertebra V2 with the head of anchor 74b abutting against washer 76b.

In one form, it is contemplated that the surface of washers 76a, 76b in contact with the head of the screw extending therethrough is concave to at least partially receive the screw head so that the profile of the screw head above washer 76a is minimized. In another form, the spiked washers are in the form of staples configured to attach the ends of the implant to the vertebrae without a bone screw.

Referring now to Fig. 10, another embodiment spine stabilization system 90 is shown attached to the anterior faces of vertebrae V1 and V2. System 90 has an implant 91

having a first end 92a and an opposite second end 92b embedded in vertebrae V1 and V2, respectively. Vertebra V1 has a first opening H1 and a first tunnel extending therefrom into vertebra V1 at an angle $+\alpha$ relative to axial plane P of the spinal column. A second opening H2 having a second tunnel extending therefrom is formed into vertebra V1 at an angle $+\alpha$ relative to axial plane P so that the second tunnel intersects the first tunnel extending from opening H1. First end 92a is positioned through first opening H1 and into the first tunnel where it is attached to vertebra V1 by a first anchor 94a.

Anchors 94a, 94b are illustrated in the form of a pin fastener having a screw thread portion with a pin 95a extending therefrom. Anchor 94a is threaded into opening H2 so that pin 95a extends through second end 92a to secure implant 91 to vertebra V1. The end of anchor 94a opposite pin 95a is provided without a head so that anchor 95a can be recessed below the anterior face of vertebra V1.

Vertebra V2 has a third opening H3 and a third tunnel extending therefrom at an angle $-\alpha$ into vertebra V2. A fourth opening H4 having a fourth tunnel extending therefrom at an angle $+\alpha$ is formed in vertebra V2 so that the fourth tunnel intersects the third tunnel extending from third opening H3. Second end 92b of implant 91 is positioned through third opening H3 and into the third tunnel where it is attached to vertebra V2 by a second anchor 94b. Anchor 94b has a screw thread with a pin 95b extending therefrom. Anchor 94b is threaded into opening H4 so that pin 95b extends through second end 92b to secure implant 91 to vertebra V2. The end of anchor 94b opposite pin 95b is provided without a head so that anchor 95b can be recessed below the outer surface of vertebra V2. Referring now to Fig. 11, implant 90 is shown with a slightly altered anchoring arrangement as compared to that of Fig. 10. The anchors 96a, 96b of Fig. 11 are illustrated in the form of a pin fastener having an exposed head that extends slightly from the anterior face of vertebra V1 and V2, respectively.

It is contemplated that the implant 91 of Figs. 10 and 11 can be provided with eyelet or other opening at each end 92a, 92b sized to receive the pin extending distally from the screw thread portion of anchors 94, 96. It is also contemplated that the pins of anchors 94, 96 can extend directly through the implant material at its ends 92a, 92b.

Referring now to Fig. 12, there is illustrated spine stabilization system 100 attached along the anterior faces of vertebrae V1 and V2. System 100 has an implant 101

with a first end 102a and opposite second end 102b. A first tunnel extends from first opening H1 posteriorly into vertebra V1, and second tunnel extends laterally from a second opening H2 formed in the lateral side of vertebra V1 and intersects the first tunnel. First end 102a extends through opening H1 and into the first tunnel. Anchors 104a, 104b are illustrated in the form of a pin fastener. A first anchor 104a has a screw thread portion with a pin 105a extending therefrom. First anchor 104a is placed through second opening H2 so that pin 105a engages first end 102a of implant 101.

A third tunnel extends from third opening H3 posteriorly into vertebra V2, and a fourth tunnel extends laterally from a fourth opening H4 formed in the lateral side of vertebra V2 and intersects the third tunnel. Second end 102b extends through opening H3 and into the third tunnel. A second anchor 104b has a screw thread portion with a pin 105b extending therefrom. Second anchor 104b is placed through fourth opening H4 so that pin 105b engages first end 102b of implant 101.

Referring now to Fig. 13, there is illustrated another embodiment spine stabilization system 110 extending along the anterior faces of vertebrae V1, V2 and having an obliquely oriented attachment arrangement in each of the vertebrae V1, V2. System 110 includes an implant 111 extending between a first end 112a and a second end 112b. First opening H1 is formed in the anterior face of vertebra V1 and has a first tunnel extending therefrom that curves obliquely relative to the sagittal plane toward the lateral face of vertebra V1. A second opening H2 is formed in the antero-lateral face of vertebra V1 and has a second tunnel extending therefrom that intersects the first tunnel. Implant 111 has a first end 112a extending through first opening H1 into the first tunnel. A first anchor 114a has a screw thread portion with a pin 115a extending therefrom. Anchor 114a is placed through opening H2 so that pin 115a engages first end 112a of implant 111. Third opening H3 is formed in the anterior face of vertebra V2 and has a first tunnel extending therefrom that curves obliquely relative to the sagittal plane toward the lateral face of vertebra V2. A fourth opening H4 is formed in the antero-lateral face of vertebra V2 and has a fourth tunnel extending therefrom that intersects the third tunnel. Implant 111 has a second end 112b extending through third opening H3. A second anchor 114b has a screw thread portion with a pin 115b extending therefrom. Anchor 114b is placed through opening H4 so that pin 115b engages first end 112b of implant 111.

Referring now to Fig. 14 another embodiment spine stabilization system 120 is attached to vertebrae V1 and V2. System 120 has an implant 121 extending along the lateral faces of vertebrae V1 and V2. Vertebra V1 has a first opening H1 in the lateral face of vertebra V1 and a first tunnel extending therefrom. First end 122a extends through first opening H1 and into the first tunnel where anchor 124a secures implant 121 to vertebra V1. Vertebra V2 has a second opening H2 in the lateral face of vertebra V2 and a second tunnel extending therefrom. Second end 122b extends through opening H2 and into the second tunnel where second anchor 124b secures implant 121 to vertebra V2. Anchors 124a, 124b are interference screws embedded in the respective vertebrae V1, V2 and in engagement with respective ones of the ends of implant 121.

Referring now to Fig. 15, there is illustrated another embodiment spine stabilization system 130 having an implant 131 extending along the lateral faces of vertebrae V1 and V2. First opening H1 is formed in the lateral face of vertebra V1 and has a first tunnel extending into vertebra V1. A second opening H2 is formed in the anterior face of vertebra V1 and has a second tunnel extending therefrom that intersects the first tunnel. Implant 131 has a first end 132a extending through first opening H1 and into the first tunnel. A first anchor 134a in the second tunnel has a screw thread portion with a pin 135a extending therefrom that engages first end 132a of implant 131.

Third opening H3 is formed in the lateral face of vertebra V2 and has a third tunnel extending therefrom into vertebra V2. A fourth opening H4 is formed in the anterior face of vertebra V2 and has a fourth tunnel extending therefrom that intersects the third tunnel. Implant 131 has a second end 132b extending through third opening H3 into the third tunnel. A second anchor 134b in the fourth tunnel has a screw thread portion with a pin 135b extending therefrom that engages second end 132b of implant 131.

Referring now to Figs. 16 and 17, further embodiments of spine stabilization systems are illustrated that employ multiple implants attached to vertebra V1 and V2. In Fig. 16 stabilization system 140 includes a first implant 141 offset laterally to a first side of the sagittal plane L, and a second implant 141' offset to a second side of the sagittal plane L. First and second implants 141, 141' can be equally spaced the same distance from plane L.

First implant 141 has a first end 142a extending through opening H1 and into a first tunnel formed in vertebra V1. First end 142a is attached to vertebra V1 with anchor 144a in the first tunnel. Implant 141 has an opposite second end 142b extending through opening H3 and into a third tunnel formed in vertebra V2. Second end 142b is attached to vertebra V2 with anchor 144b in the third tunnel.

Second implant 141' has a first end 142a' extending through opening H2 and into a second tunnel in vertebra V1. First end 142a' is attached to vertebra V1 with anchor 144a' in the second tunnel. Implant 141' has an opposite second end 142b' extending through opening H4 and into a fourth tunnel in vertebra V2. Second end 142b' is attached to vertebra V2 with anchor 144b' in the fourth tunnel.

In Fig. 17 stabilization system 150 is secured anteriorly to vertebrae V1 and V2. System 150 has a first implant 151 with a first end 152a extending through opening H1 and into a first tunnel formed in vertebra V1. First end 152a is attached to vertebra V1 with anchor 154a in the first tunnel. Implant 151 has an opposite second end 152b extending across sagittal plane L and through opening H4 and into a fourth tunnel formed in vertebra V2. Second end 152b is attached to vertebra V2 with anchor 154b in the fourth tunnel.

Stabilization system 150 has a second implant 151' with a first end 152a' extending through opening H2 and into a second tunnel formed in vertebra V1. First end 152a' is attached to vertebra V1 with anchor 154a' in the second tunnel. Implant 151' has an opposite second end 152b' extending through opening H3 and into a third tunnel formed in vertebra V2. Second end 152b' is attached to vertebra V2 with anchor 154b' in the third tunnel. Second implant 151' extends obliquely across sagittal plane L, forming an "X" shape with first implant 151. The angle of each implant 151, 151' relative to the sagittal plane may vary in the range from about 5 degrees to about 86 degrees, from about 20 degrees to about 70 degrees, and from about 30 degrees to about 60 degrees. The criss-crossing of implants 151, 151' improves the resistance of spinal stabilization system 150 to relative rotation or lateral bending between vertebrae V1 and V2.

Referring now to Fig. 18 there is illustrated another embodiment of spinal stabilization system 160 attached to vertebrae V1 and V2. System 160 has an implant 161 bendable or flexible to assume a U-shaped configuration, and is attachable to the anterior,

antero-lateral or lateral faces of vertebrae V1 and V2. A curved or non-linear tunnel is formed in vertebra V1 between openings H1 and H2 in the anterior face of vertebra V1. Vertebra V2 has formed therein a first tunnel extending from opening H3, and a second tunnel extending from opening H4. Implant 161 extends through the curved tunnel of vertebra V1, and has a first end 162a secured in the tunnel extending from opening H3 with first anchor 164a. Implant 161 has a second end 162b secured in the tunnel extending from opening H4 with second anchor 164b.

Referring now to Fig. 19 there is illustrated another spinal stabilization system 170 attached to vertebrae V1 and V2. System 170 has an implant 171 bendable or flexible to assume an oval-shaped configuration, and is attachable to the anterior, antero-lateral or lateral faces of vertebrae V1 and V2. A first curved or non-linear tunnel is formed in vertebra V1 between openings H1 and H2 in the anterior face of vertebra V1. A second curved or non-linear tunnel is formed in vertebra V2 between openings H3 and H4 in the anterior face of vertebra V2. Implant 171 extends through the first tunnel of vertebra V1, and has a first end 172a positioned in the second tunnel of vertebra V2. Implant 171 has a second end 172b positioned in the second tunnel adjacent to or in overlapping arrangement with first end 172a. An anchor 174 secures ends 172a, 172b in the second tunnel of vertebra V2.

Referring now to Fig. 20, there is shown another embodiment stabilization system 180 secured to the posterior portion of the spine. System 180 has an implant 181 that extends between and is attached to the spinous processes SP1 and SP2 of vertebra V1 and V2 with anchors 184a and 184b, respectively. Anchors 184a and 184b are illustrated as buttons or buckles such as described above with respect to button 54. Tunnels can be drilled through each of the spinous processes SP1, SP2 sized to receive the ends of implant 181 therethrough for attachment to anchors 184a, 184b. Alternatively, the tunnels through SP1 and SP2 can be sized to receive an attachment loop or member extending from respective ones of the anchors 184a, 184b for engagement of the ends of implant 181 between SP1 and SP2.

In Fig. 21, another embodiment posterior spine stabilization system 190 is illustrated. Vertebra V1 includes a first tunnel formed in a pedicle thereof opening at H1 on the pedicle at the posterior portion of the spinal column segment. Vertebra V2 includes

a second tunnel formed in or through a pedicle thereof and opening at H2 on the pedicle at the posterior portion of the spinal column segment. System 190 includes an implant 191 extending between and attached to the pedicles P1 and P2 of vertebra V1 and V2. Implant 191 includes a first end 191a embedded in the first tunnel in vertebra V1 and attached thereto with anchor 194a. Implant 191 includes a second end 191b embedded in the second tunnel in vertebra V2 and attached thereto with anchor 194b. Anchors 194a and 194b are illustrated as threaded interference screws. However, other embodiments contemplate the use of other anchors described herein. Other embodiments also contemplate the attachment of posterior spine stabilization devices to the facets, pars, or transverse processes of vertebrae V1 and V2.

Referring now to Fig. 22, a posterior view is provided of the posterior portion of the spinal column segment with a spine stabilization system 200 attached thereto along multiple levels. System 200 is similar to system 190 described above, and includes a first implant 201 attached to the pedicles of vertebrae V1 and V3 via anchors 204a and 204c, respectively, along one side of the spinous processes. The ends of implants 201 and anchors 204a, 204c can be embedded or positioned in tunnels formed in the pedicles of vertebra V1, V3. Spine stabilization system 200 further includes a second implant 200' attached to the pedicles of vertebrae V1 and V3 via anchors 204a' and 204c', respectively, along the other side of the spinous processes opposite implant 200. The ends of implant 201' and anchors 204a', 204c' can be embedded or positioned in tunnels formed in the pedicles of vertebra V1, V3. Implants 201, 201' can span across vertebra V2, or can be attached thereto with an anchor extending through or coupled to the implant.

The present invention further contemplates surgical methods for attaching a spinal stabilization system to first and second vertebrae. The openings and tunnels can be formed by drilling, tapping, chiseling, punching, or otherwise cutting the vertebral bodies. In the embodiments of the stabilization system employing curved or non-linear tunnels through the vertebrae, it is contemplated that a flexible drill can be used to create these curved tunnels. It is further contemplated that attachment of the stabilization systems could occur before, after or during placement of a device into the disc space between the first and second vertebrae.

In one specific application, the stabilization system is used to reconstruct the anterior longitudinal ligament. In one specific surgical technique, the disc space is accessed from an anterior approach and a fusion device, artificial disc or spacer is inserted into the disc space. A first opening and tunnel is formed into the upper vertebral body and a second opening and tunnel is formed into the lower vertebral body. One end of the implant is inserted into either the first or second tunnel, and the implant is attached to the corresponding vertebra with an anchor. The opposite end of the implant is inserted into the other tunnel formed in the other vertebra and attached with an anchor. A desired tension can be applied to the implant before attachment of the other end to the other vertebra. The applied tension may differ depending on whether the device inserted into the disc space is a fusion cages, an artificial disc, or spacer. The other end of the implant is then attached to the other vertebra using a second anchor. The anchors can be embedded in the vertebrae to reduce the profile of the system along the upper and lower vertebrae.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the illustrated embodiments have been shown and described, and that all changes and modifications that come within the spirit of the invention are desired to be protected. For example, the spine stabilization system could be employed across multiple vertebral levels. In another example, multiple spine stabilization systems could be employed on the same vertebral level such as across the anterior aspects and the lateral aspects of the same vertebrae.

What is claimed is:

1. A spine stabilization system, comprising:

an implant having a first end and an opposite second end, at least a portion of one of said
first and second ends positioned in a tunnel formed in a first vertebral body; and
at least one anchor engaged to the first vertebral body attaching said one end of said
implant to the first vertebral body.

2. The system of claim 1, wherein said at least one anchor is embedded in the tunnel.

3. The system of claim 1, wherein the other of said first and second ends of said
implant is embedded in a second tunnel formed in a second vertebral body and further
comprising a second anchor engaged to the second vertebral body attaching said implant
to the second vertebral body.

4. The system of claim 3, further comprising a device positioned in a spinal disc
space between the first vertebral body and the second vertebral body.

5. The system of claim 1, wherein the tunnel forms an angle relative to the axial plane
of the spinal column in the range of 0 degrees to 80 degrees.

6. The system of claim 5, wherein said angle is in the range of about 25 degrees to
about 65 degrees.

7. The system of claim 1, wherein said at least one anchor is selected from the group
consisting of: an interference screw, a suture anchor, a button, a spiked washer, and a pin
fastener.

8. The system of claim 3, wherein said implant is an artificial ligament.

9. The system of claim 8, wherein said artificial ligament extends along the anterior faces of the first vertebral body and the second vertebral body.

10. The system of claim 8, wherein said artificial ligament extends along the lateral
5 faces of the first vertebral body and the second vertebral body.

11. The system of claim 8, wherein said artificial ligament extends between a pedicle of the first vertebral body and a pedicle of the second vertebral body.

10 12. The system of claim 8, wherein said artificial ligament comprises a synthetic resorbable material selected from the group consisting of: polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass and combinations thereof.

15 13. The system of claim 8, wherein said artificial ligament comprises a natural resorbable material selected from the group consisting of: autograft, allograft, xenograft, soft tissues, connective tissues, demineralized bone matrix, and combinations thereof.

20 14. The system of claim 8, wherein said artificial ligament comprises a nonresorbable material selected from the group consisting of: polyethylene, polyester, polyvinyl alcohol, polyacrylonitrile, polyamide, polytetrafluorethylene, poly-paraphenylene terephthalamide, cellulose, shape-memory alloys, titanium, titanium alloys, stainless steel, and combinations thereof.

25 15. The system of claim 1, wherein said at least one anchor is positioned in a second tunnel that intersects the tunnel in which said one end of said implant is positioned.

30 16. The system of claim 15, wherein the tunnel extends from an anterior face of the first vertebral body and the second tunnel extends from a lateral face of the first vertebral body.

17. The system of claim 15, wherein the tunnel extends from an anterior face of the first vertebral body and the second tunnel extends from an antero-lateral face of the first vertebral body.

18. The system of claim 17, wherein the tunnel is curved toward the second tunnel and the second tunnel extends obliquely relative to the saggital plane.

19. The system of claim 15, wherein:
the tunnel extends from an anterior face of the first vertebral body adjacent one vertebral endplate at a first angle relative to the axial plane of the spinal column; and
the second tunnel extends from the anterior face of the first vertebral body adjacent the other endplate at a second angle relative to the axial plane of the spinal column.

20. The system of claim 19, wherein said first angle and said second angle are equal.

21. The system of claim 1, wherein:
the tunnel extends through the first vertebral body from a first opening adjacent one endplate of the first vertebral body to a second opening adjacent the other endplate of the first vertebral body; and
said one end of said implant extends from the first opening through the tunnel and is attached to the first vertebral body at the second opening with said at least one anchor.

22. The system of claim 21, wherein said at least one anchor is a button positioned against the first vertebral body at the second opening.

23. The system of claim 21, wherein said first opening opens at the one vertebral endplate.

24. The system of claim 1, further comprising:

a second implant having a first end and an opposite second end, at least a portion of said first and second ends of the second implant positioned in a second tunnel formed in the first vertebral body; and

5 a second anchor engaged to the first vertebral body attaching said second implant to the first vertebral body.

25. The system of claim 24, wherein:

10 said implant is attached along the anterior face of the first vertebral body on one side of the sagittal plane; and

said second implant is attached along the anterior face of the first vertebral body on the other side of the sagittal plane.

26. The system of claim 24, wherein:

15 at least a portion of the other of said first and second ends of said implant is positioned in a third tunnel formed in a second vertebral body and further comprising a third anchor attaching said implant to the second vertebra; and

20 at least a portion of the other of said first and second ends of said second implant is positioned in a fourth tunnel formed in the second vertebral body and further comprising a fourth anchor attaching said second implant to the second vertebra.

27. The system of claim 26, wherein said implant and said second implant are parallel to one another.

25 28. The system of claim 26, wherein said implant and said second implant cross over one another.

29. The system of claim 26, wherein each of said at least one anchor, said second anchor, said third anchor and said fourth anchor are interference screws position in
30 respective ones of the tunnel, the second tunnel, the third tunnel, and the fourth tunnel in engagement with the respective ends of said implant and said second implant.

30. The system of claim 1, further comprising:

a second tunnel formed in the first vertebral body and spaced from the tunnel;

a third tunnel extending through a second vertebral body from a first opening adjacent one
endplate of the second vertebral body to a second opening adjacent the one endplate of
the second vertebral body, wherein said implant extends through the third tunnel and at
least a portion of the other of said first and second ends is positioned in the second tunnel,
and further comprising a second anchor engaged to the first vertebral body attaching said
other end of said implant to the first vertebral body.

31. The system of claim 1, wherein the tunnel extends between a first opening adjacent
an endplate of the first vertebral body and a second opening adjacent the endplate of the
first vertebral body, and further comprising a second tunnel extending through a second
vertebral body from a third opening adjacent one endplate of the second vertebral body to
a fourth opening adjacent the one endplate of the second vertebral body, wherein said
implant extends through the second tunnel and the other of said first and second ends
extends into the first tunnel and overlaps said one end of said implant attached to the first
vertebral body.

32. The system of claim 1, further comprising a notch formed in the first vertebral
body, the tunnel extending from an opening formed in the notch, wherein said at least one
anchor is positioned in the notch.

33. The system of claim 1, wherein said at least one anchor extends along said one end
of said implant.

34. The system of claim 1, wherein said at least one anchor intersects said one end of
said implant.

35. The system of claim 1, wherein said at least one anchor is attached to said one end
of said implant.

36. The system of claim 1, further comprising a second tunnel formed in the first vertebral body spaced from the tunnel, and wherein said one end of said implant has a second portion positionable in the second tunnel and attached thereto with a second anchor engaged to the first vertebral body.

37. The system of claim 1, wherein said implant comprises a substantially inelastic material.

38. The system of claim 1, wherein said implant comprises a substantially flexible material.

39. A method for stabilizing a portion of the spinal column, comprising:
providing an implant having a first end and an opposite second end;
forming a tunnel in a first vertebral body;
placing at least a portion of one the first end and the second end of the implant in the tunnel; and
attaching the one end of the implant to the first vertebral body.

40. The method of claim 39, wherein forming the tunnel includes forming the tunnel at an angle relative to the axial plane of the spinal column in the range of 0 degrees to 80 degrees.

41. The method of claim 39, wherein attaching the one end includes placing at least one anchor in the tunnel in the first vertebral body.

42. The method of claim 41, further comprising:
forming a second tunnel in a second vertebral body;
placing the other of the first end and the second end of the implant in the second tunnel;
and
attaching the other end of the implant in the second tunnel of the second vertebral body.

43. The method of claim 42, wherein attaching the other end includes placing at least one anchor in the second tunnel in the second vertebral body.

5 44. The method of claim 42, wherein the first tunnel and the second tunnel are formed such that the implant extends along the anterior faces of the first vertebral body and the second vertebral body.

10 45. The method of claim 42, wherein the first tunnel and the second tunnel are formed such that the implant extends along the lateral faces of the first vertebral body and the second vertebral body.

15 46. The method of claim 42, wherein the first tunnel and the second tunnel are formed such that the implant extends along the posterior of the first vertebral body and the second vertebral body.

47. The method of claim 42, further comprising inserting a device in a spinal disc space between the first vertebral body and the second vertebral body.

20 48. The method of claim 39, further comprising:
forming a second tunnel in the first vertebral body that intersects the tunnel; and
inserting at least one anchor in the second tunnel to attach the implant.

25 49. The method of claim 48, wherein forming the tunnel includes forming the tunnel in communication with the anterior face of the first vertebral body, and forming the second tunnel includes forming the second tunnel in communication with the lateral face of the first vertebral body.

30 50. The method of claim 48, wherein forming the tunnel includes forming the tunnel in communication with the anterior face of the first vertebral body, and forming the second

tunnel includes forming the second tunnel in communication with the antero-lateral face of the first vertebral body.

51. The method of claim 48, wherein:

5 forming the tunnel includes forming the tunnel in communication with the anterior face of the first vertebral body adjacent one of its endplates and at a first angle relative to the axial plane of the spinal column; and

10 forming the second tunnel includes forming the second tunnel in communication with the anterior face of the first vertebral body adjacent the other of its endplates at a second angle relative to the axial plane.

52. The method of claim 39, wherein:

15 forming the tunnel includes forming the tunnel from a first opening adjacent one endplate of the first vertebral body to a second opening adjacent the other endplate of the first vertebral body;

placing the implant includes placing the one end of the implant through the first opening and the tunnel to the second opening; and

attaching the one end includes attaching the one end of the implant at the second opening.

20 53. The method of claim 52, wherein the first opening extends through the one endplate.

54. The method of claim 39, further comprising:

providing a second implant having a first end and an opposite second end;

25 forming a second tunnel in the first vertebral body;

placing at least portion of one of the first end and second end of the second implant into the second tunnel; and

attaching the one end of the second implant to the first vertebral body.

30 55. The method of claim 54, further comprising:

forming a third tunnel in a second vertebral body;

placing the other of the first and second ends of the implant in the third tunnel;
attaching the other end of the implant to the second vertebral body;
forming a fourth tunnel in the second vertebral body;
placing the other of the first end and second end of the second implant in the fourth tunnel;
5 and
attaching the other end of the second implant to the second vertebral body.

56. The method of claim 55, wherein the first and second implants are attached to the first and second vertebral bodies in a parallel arrangement.

57. The method of claim 55, wherein the first and second implants are attached to the first and second vertebral bodies in an X-shaped arrangement.

58. The method of claim 39, further comprising:

forming a second tunnel formed in the first vertebral body spaced from the tunnel;
forming a third tunnel in a second vertebral body from a first opening adjacent one endplate of the second vertebral body to a second opening adjacent the one endplate of the second vertebral body;
placing the implant through the third tunnel;
placing the other of the first end and second end of the implant into the second tunnel; and
attaching the other end in the second tunnel to the first vertebral body.

59. The method of claim 39, wherein:

forming the tunnel includes forming the tunnel between a first opening adjacent one endplate of the first vertebral body and a second opening adjacent the one endplate of the first vertebral body, and further comprising:
forming a second tunnel through a second vertebral body from a third opening adjacent one endplate of the second vertebral body to a fourth opening adjacent the one endplate of the second vertebral body;
placing the implant through the second tunnel;
placing the one end of the implant into the tunnel through the first opening;

placing the other of said first and second ends of the implant into the tunnel through the second opening and adjacent the one end of the implant in the first tunnel; and attaching the first and second ends to the first vertebral body.

5

60. The method of claim 39, further comprising:
forming a notch in the first vertebral body;
forming the tunnel includes forming the tunnel in communication with the notch; and
attaching the one end to the first vertebral body in the notch.

10

61. A spine stabilization system, comprising:
an implant having a first end with at least a portion of said first end positionable in a first tunnel formed in a first vertebral body, said implant having a second end positionable in a second tunnel formed in a second vertebral body; and
a first anchor engageable to said first end of said implant in the first tunnel of the first vertebral body; and
a second anchor engageable to said second end of said implant in the second tunnel of the second vertebral body.

15

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62. The system of claim 61, wherein said implant, said first anchor, and said second anchor are each made from resorbable material.

63. The system of claim 61, wherein said implant, said first anchor and said second anchor are each made from nonresorbable material.

25

64. The system of claim 61, wherein the first tunnel in the first vertebral body and the second tunnel in the second vertebral body each form an angle relative to the axial plane.

65. The system of claim 61, wherein said implant extends along the anterior faces of the first vertebral body and the second vertebral body.

30

66. The system of claim 61, wherein said implant extends along the lateral faces of the first vertebral body and the second vertebral body.

67. The system of claim 61, wherein said artificial ligament extends between a pedicle of the first vertebral body and a pedicle of the second vertebral body.

68. The system of claim 61, wherein said first anchor is positioned in a third tunnel in the first vertebral body that intersects the first tunnel and said second anchor is positioned in a fourth tunnel in the second vertebral body that intersects the second tunnel.

69. The system of claim 68, wherein the first and second tunnels each extend from an anterior face of the first vertebral body and second vertebral body, respectively, and the third and fourth tunnels each extend from a lateral face of the first vertebral body and the second vertebral body, respectively.

70. The system of claim 68, wherein:
the first tunnel extends from an anterior face of the first vertebral body adjacent one endplate at a first angle relative to the axial plane of the spinal column; and
the third tunnel extends from the anterior face of the first vertebral body adjacent the other endplate at a second angle relative to the axial plane of the spinal column;
the second tunnel extends from an anterior face of the second vertebral body adjacent one endplate at a third angle relative to the axial plane of the spinal column; and
the fourth tunnel extends from the anterior face of the first vertebral body adjacent the other endplate at a fourth angle relative to the axial plane of the spinal column.

71. The system of claim 61, wherein:
the first tunnel extends through the first vertebral body from a first opening adjacent one endplate of the first vertebral body to a second opening adjacent the other endplate of the first vertebral body; and
said first end of said implant extends from the first opening through the first tunnel and is attached to the first vertebral body at the second opening with said first anchor;

the second tunnel extends through the second vertebral body from a third opening adjacent one endplate of the second vertebral body to a fourth opening adjacent the other endplate of the second vertebral body; and

said second end of said implant extends from the third opening through the second tunnel and is attached to the second vertebral body at the fourth opening with said second anchor.

72. The system of claim 61, wherein said first anchor extends along said first end of said implant and said second anchor extends along said second end of said implant.

73. The system of claim 61, wherein said first anchor intersects said first end of said implant and said second anchor intersects said second end of said implant.

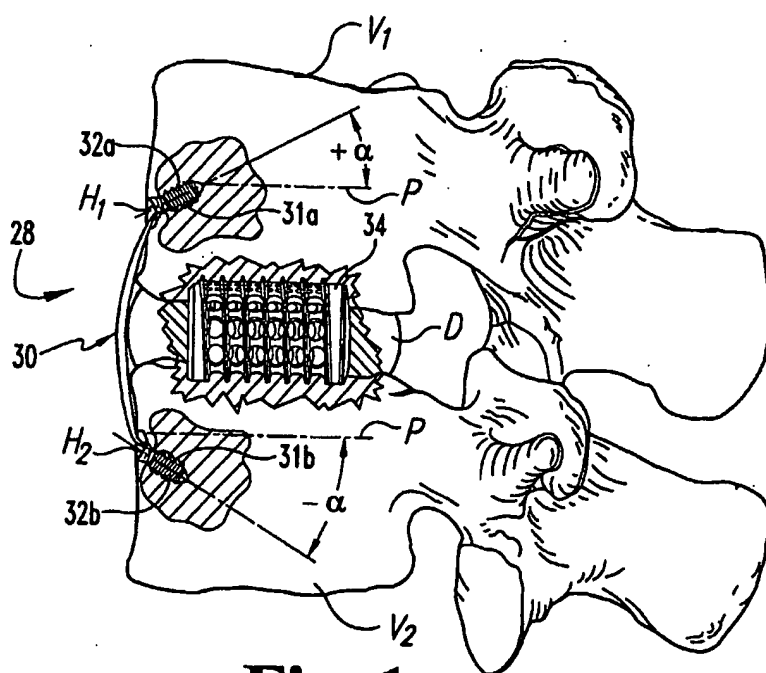
74. The system of claim 61, wherein said first anchor is attached to said first end of said implant and said second anchor is attached to said second end of said implant.

75. The system of claim 61, wherein said implant includes a first segment attached to the first vertebral body and a second segment attached to the second vertebral body, said first segment and said second segment being coupled to one another.

76. The system of claim 61, wherein said implant comprises a substantially inelastic material.

77. The system of claim 61, wherein said implant comprises a substantially flexible material.

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**Fig. 1**

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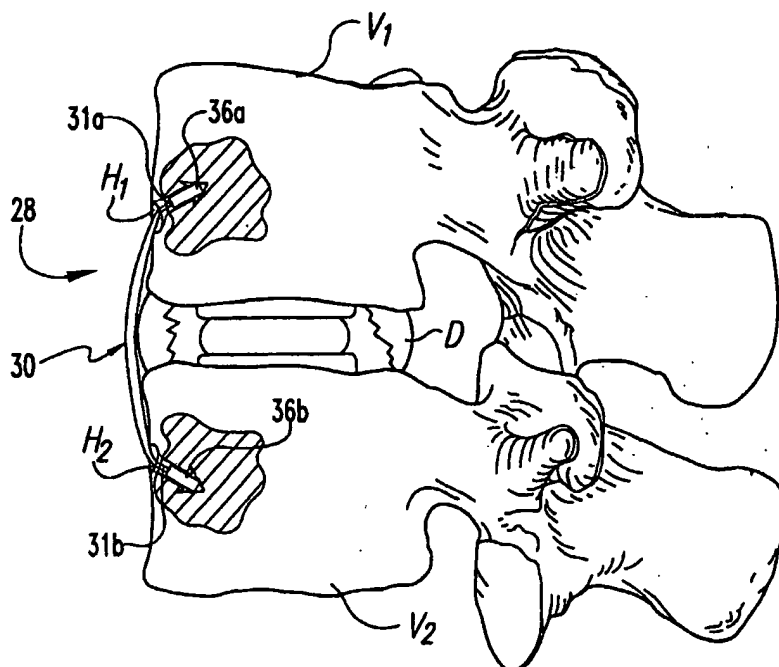


Fig. 2

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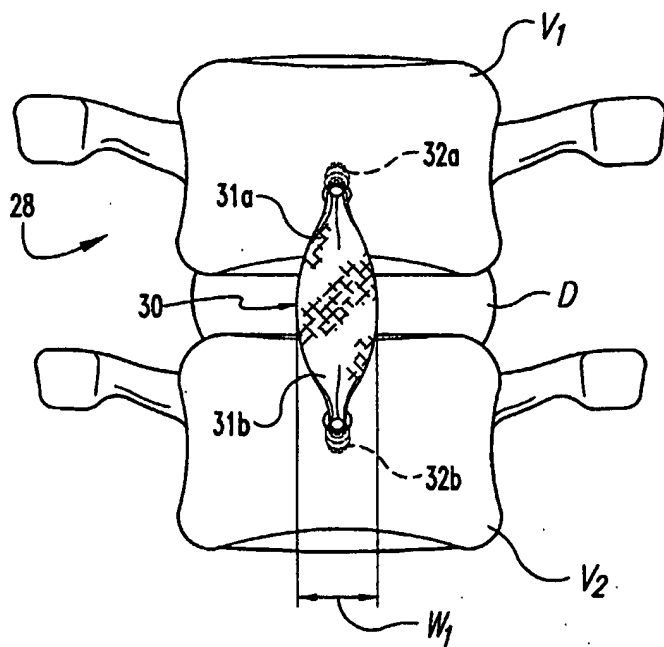


Fig. 3

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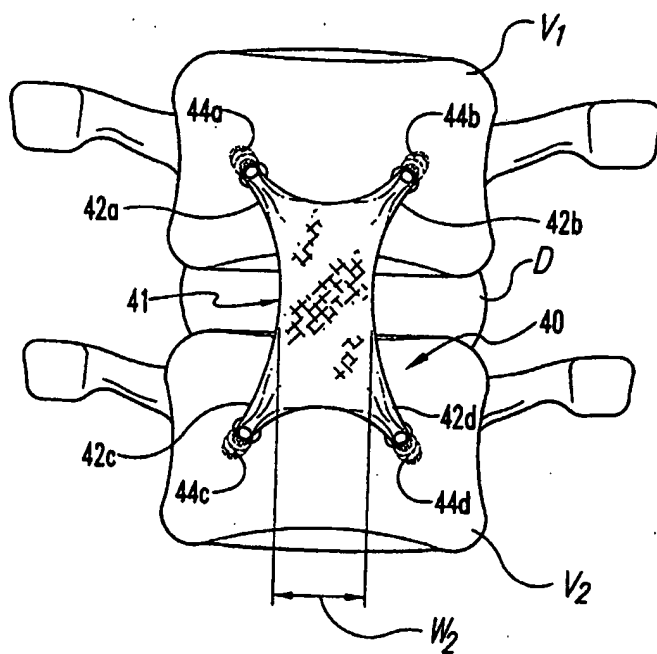


Fig. 4

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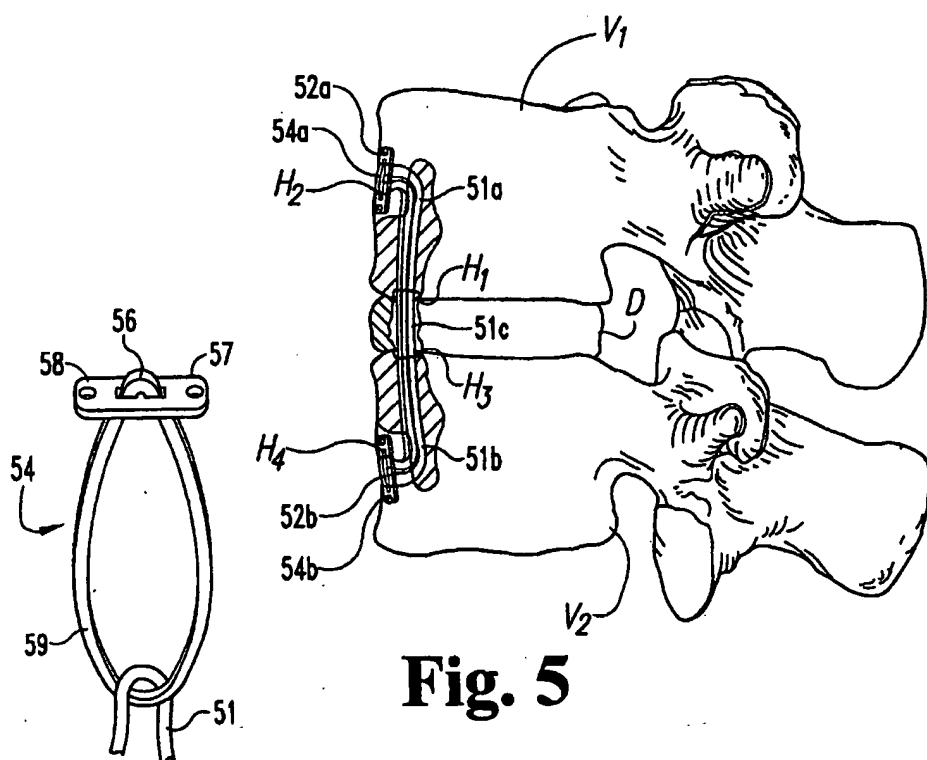
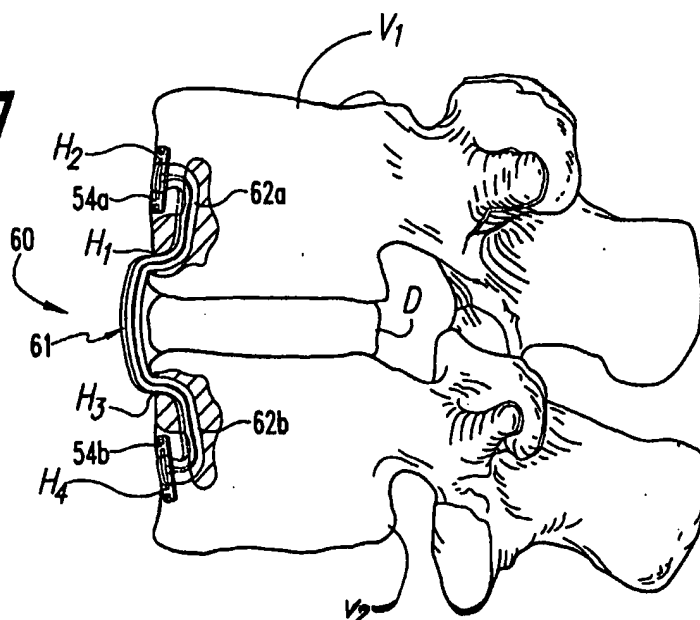
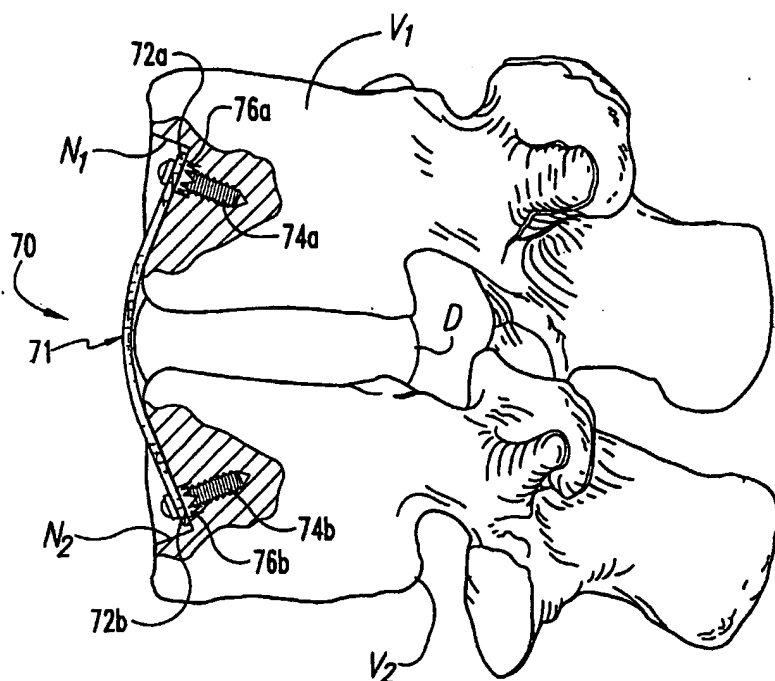
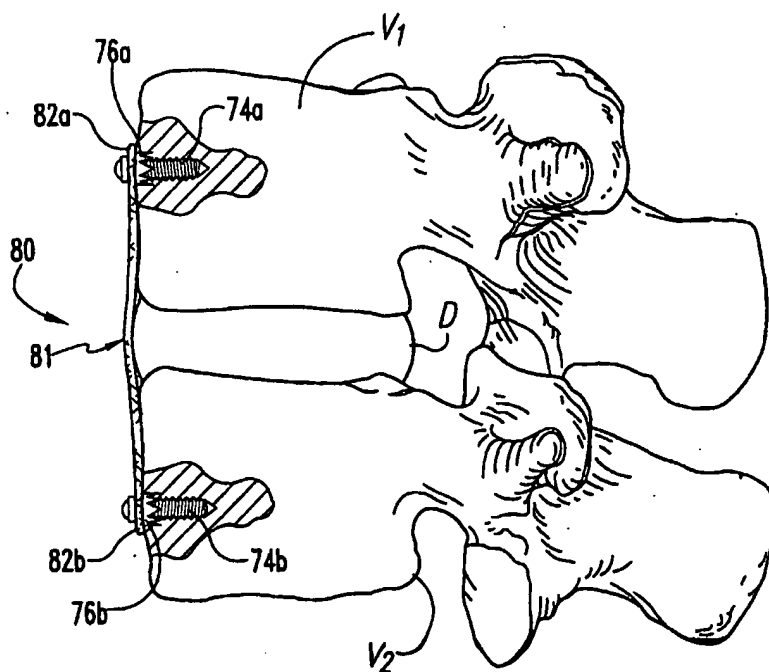


Fig. 7



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**Fig. 8****Fig. 9**

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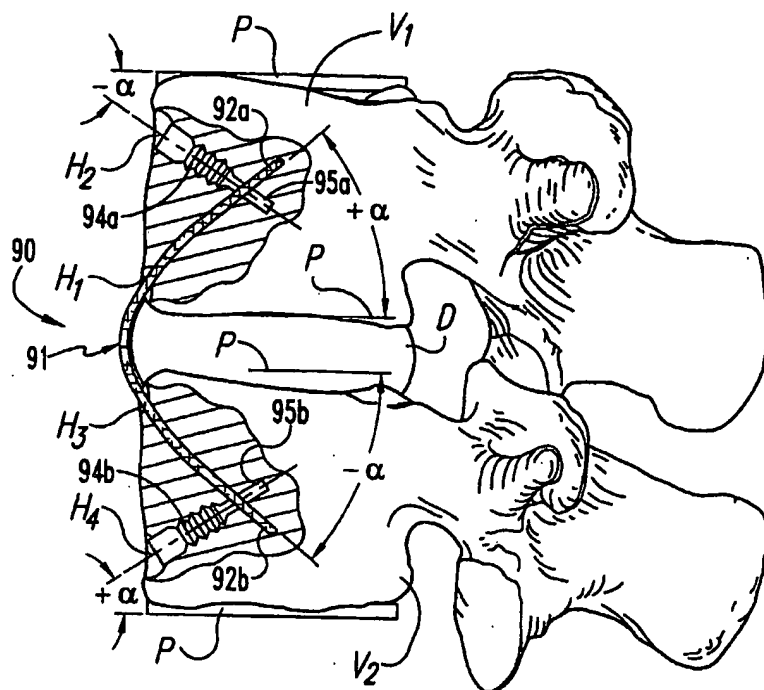


Fig. 10

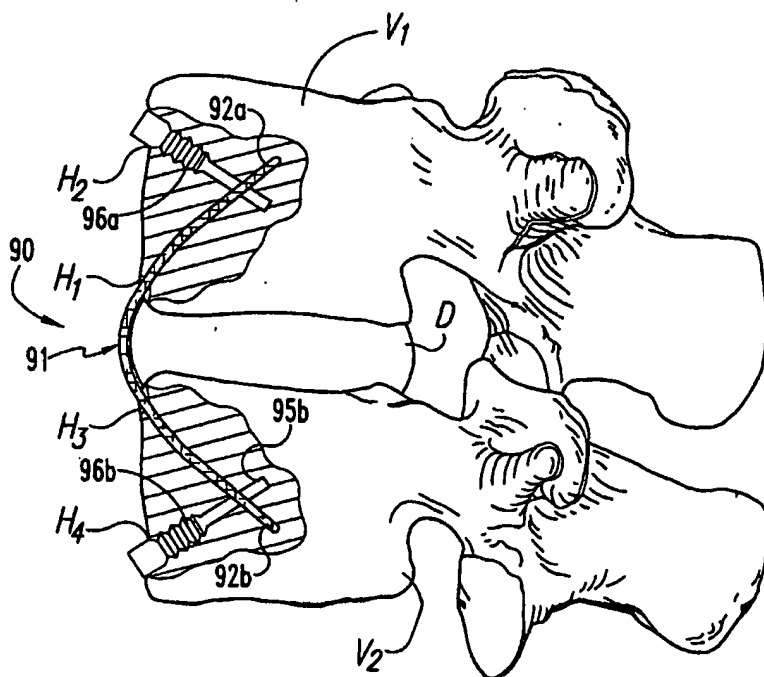
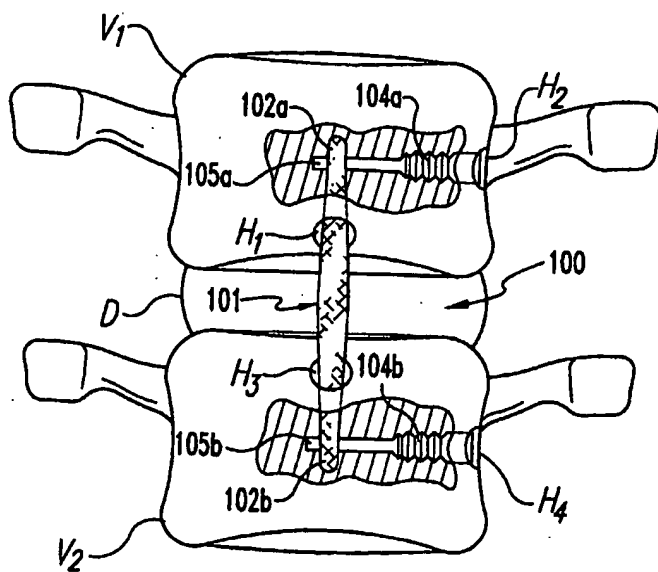
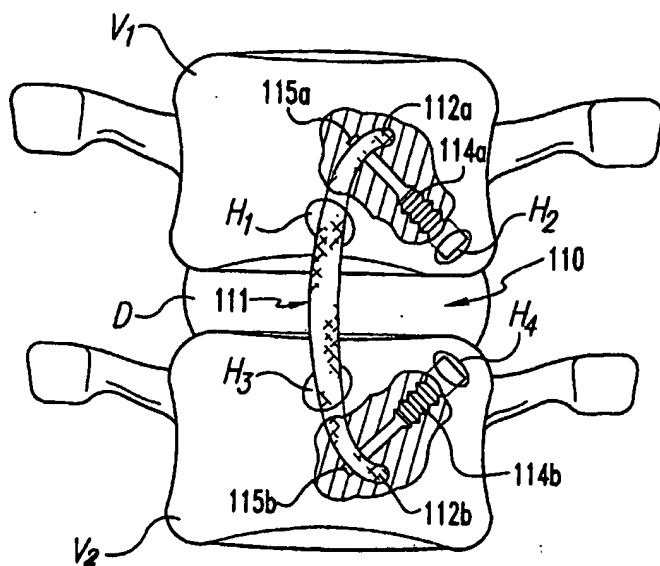


Fig. 11

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**Fig. 12****Fig. 13**

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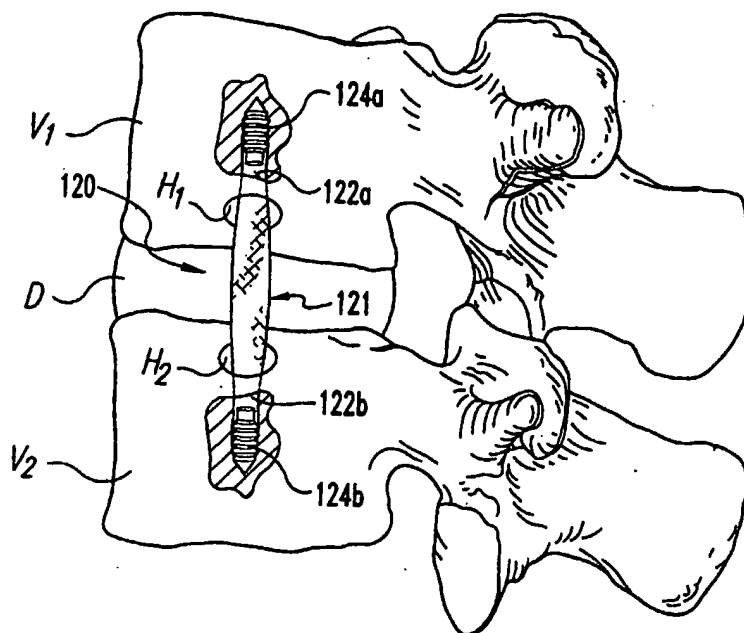


Fig. 14

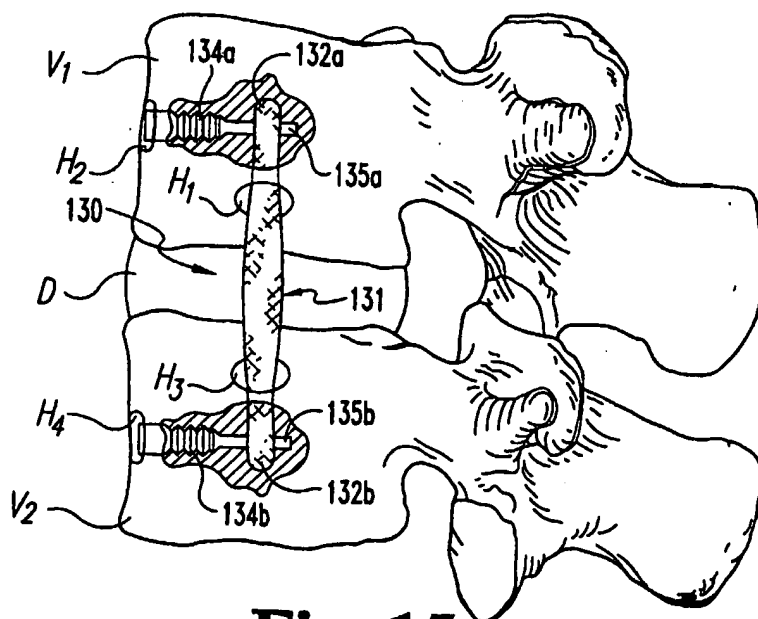


Fig. 15

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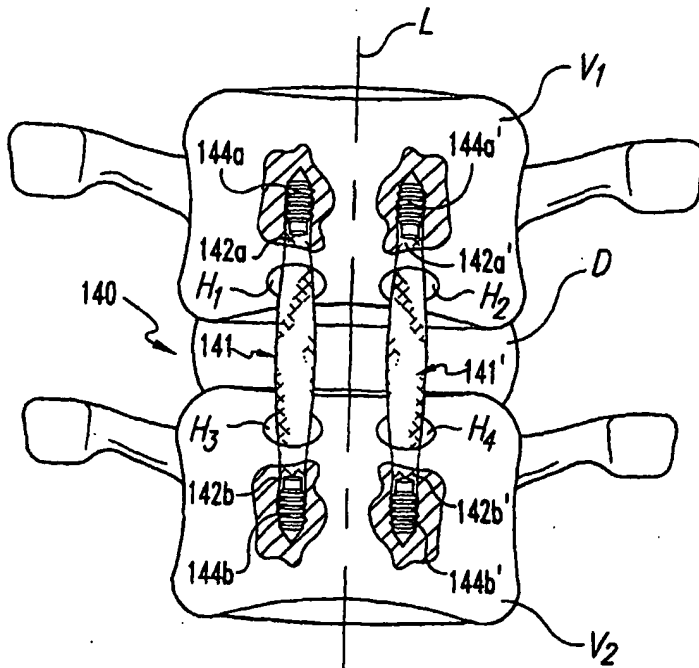


Fig. 16

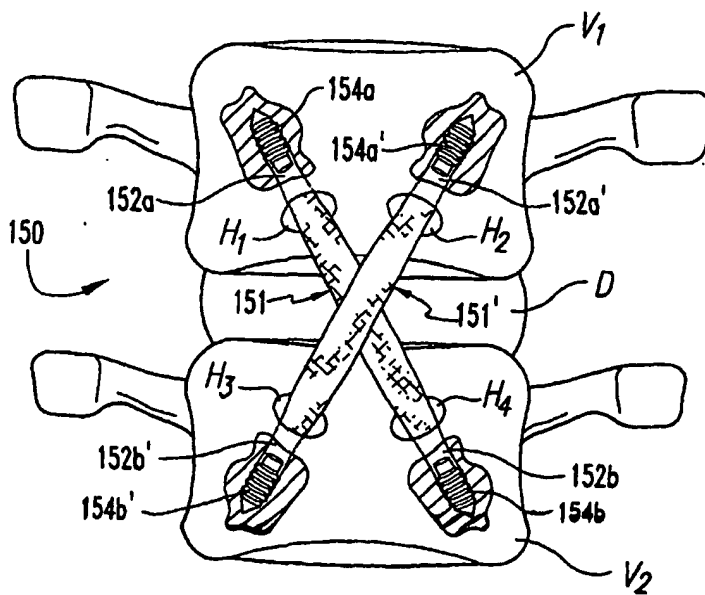


Fig. 17

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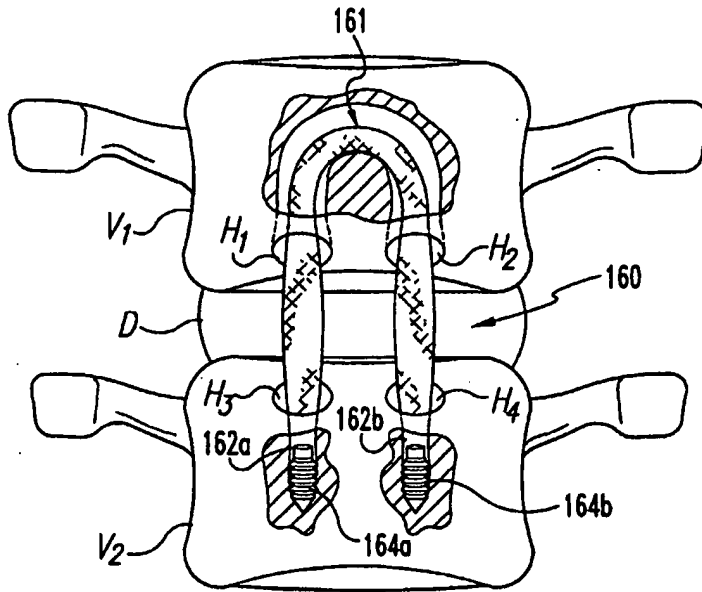


Fig. 18

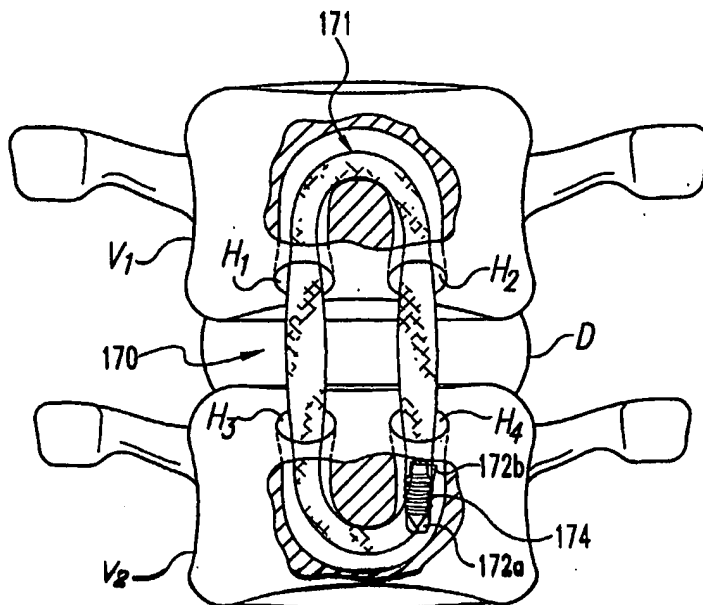
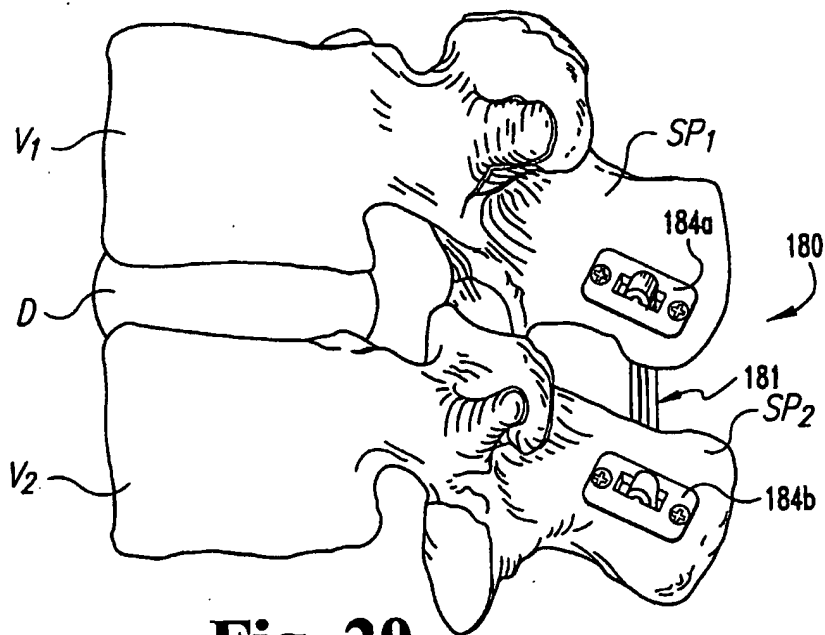
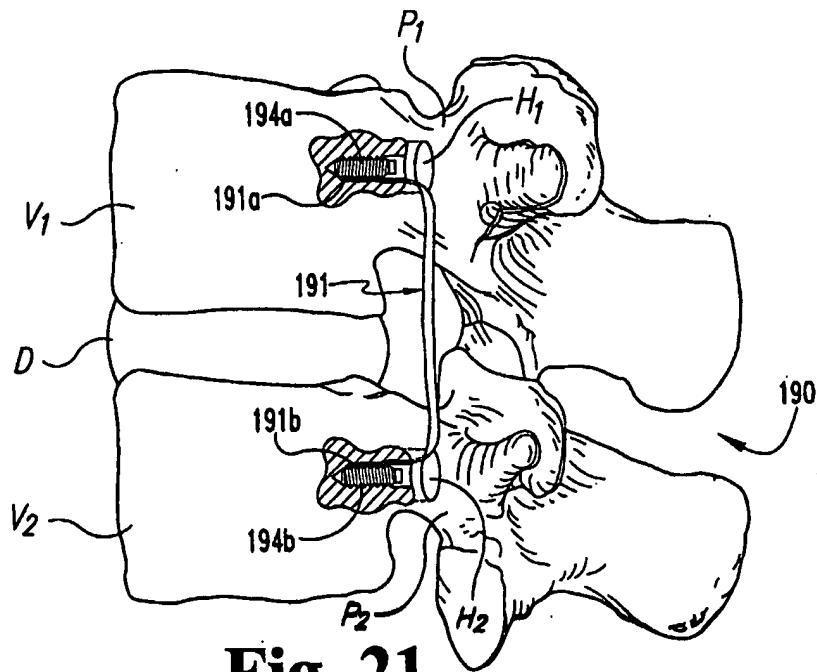
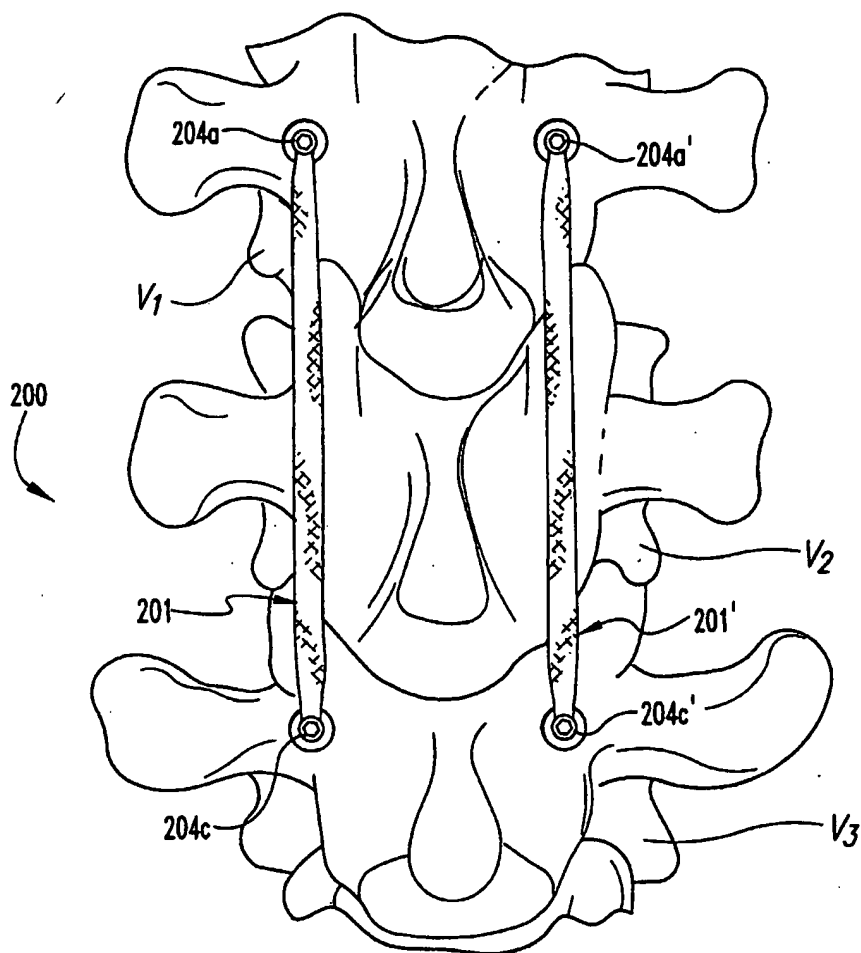


Fig. 19

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**Fig. 20****Fig. 21**

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**Fig. 22**

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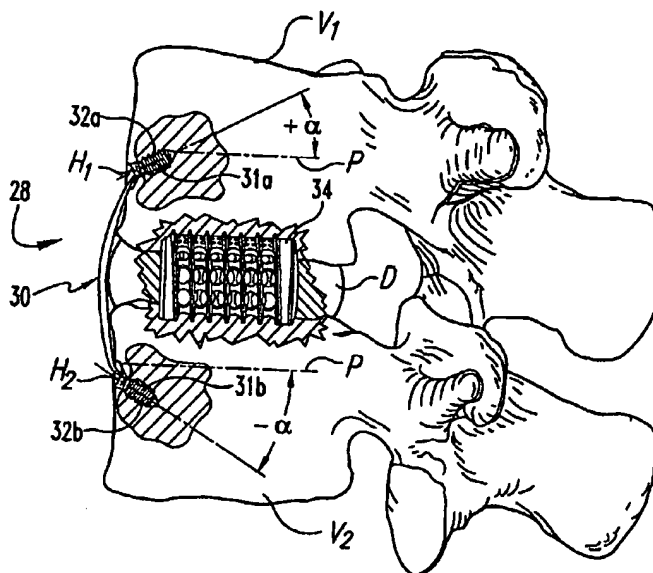
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(54) Title: FLEXIBLE SYSTEMS FOR SPINAL STABILIZATION AND FIXATION



(57) Abstract: Systems for spinal stabilization and fixation replace or augment spinal ligamentous and/or bony tissues. The systems comprise an implant (30), at least a portion of one end (31a), which can be positioned in a tunnel (H1) formed in a first vertebral body (V1), and at least one anchor (32a) for attaching said one end to said first vertebral body. The second end (31b) of the implant may be positionable in a second tunnel (H2) formed in a second vertebral body (V2), in which case the system also comprises a second anchor (32b) engaged to said second end in said second tunnel. The systems have a low profile conformable to spinal anatomy.



(88) Date of publication of the international search report:
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/06138

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 67651 A (HIGHGATE ORTHOPEDICS) 16 November 2000 (2000-11-16)	1-23, 30-38, 61-77
Y	page 7, line 17 - line 25 page 8, line 6 - line 8 page 8, line 21 - line 22 page 22, line 19 - line 25 page 25, line 1 - line 10 page 26, line 25 - page 27, line 20 figures 6A, 6C, 9-10 --- -/--	24-29



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/06138

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	FR 2 709 410 A (JBS) 10 March 1995 (1995-03-10) figures 1, 2, 6 -----	1, 61

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/06138

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 39-60
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/06138

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